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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/687,327	10/16/2003	RameshBabu Boga	KCX-842 (19559)	8506
22827 DORITY & MA	7590 05/12/200 ANNING, P.A.	EXAMINER		
POST OFFICE	BOX 1449	PORTNER, VIRGINIA ALLEN		
GREENVILLE, SC 29602-1449			ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)				
	10/687,327	BOGA ET AL.				
Office Action Summary	Examiner	Art Unit				
	GINNY PORTNER	1645				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).						
Status						
1)⊠ Responsive to communication(s) filed on <u>20 De</u>	ecember 2007					
	action is non-final.					
<i>,</i> —	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is					
	closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.					
Disposition of Claims						
4) Claim(s) 60,64,65,67-72,74 and 76-83 is/are pending in the application. 4a) Of the above claim(s) 82 is/are withdrawn from consideration.						
5) Claim(s) is/are allowed.						
<u></u>						
6) Claim(s) 60,64,65,67-72,74 and 76-81,83 is/are rejected.						
7) Claim(s) is/are objected to.						
8) Claim(s) are subject to restriction and/or	election requirement.					
Application Papers						
9)☐ The specification is objected to by the Examiner.						
10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.						
Applicant may not request that any objection to the	drawing(s) be held in abeyance. See	e 37 CFR 1.85(a).				
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).						
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority under 35 U.S.C. § 119						
 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 						
Attachment(s)						
1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Discreption of Draftsperson's Patent Drawing Review (PTO-948) Paper No(s)/Mail Date						
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) 5) ☐ Notice of Informal Patent Application						
Paper No(s)/Mail Date 6) Other:						

DETAILED ACTION

Claims 60,64,65,67-72,74 and 76-83 are pending.

Objections/Rejections Withdrawn

- 1. Withdrawn, Double Patenting: The rejection of claims 60-81 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 23-48 of copending Application No. 10/687,270 is herein withdrawn in light of the effective terminal disclaimer filed in Applicant's response dated December 20, 2008.
- 2. Withdrawn, Claim 60, 66,71-72, 79 rejected under 35 U.S.C. 103(a) as being unpatentable over Sunstar, KK (JP 6215177 (English abstract) in view of US Pat. 5,174,959, is herein withdrawn in light of the amendment of claim 60 to incorporate the combination of claim limitations in claim 63, a claim which Sunstar in view of 5174959 was not applied.
- 3. Withdrawn, Claims 60,66, 73, 75, 79 rejected under 35 U.S.C. 103(a) as being unpatentable over Delente (US Pat. 5,432,094) in view of Arai et al (US PG Pub 2002/0068364) and US Pat. 4,407960, is herein withdrawn in light of the amendment of claim 60 to incorporate the combination of claim limitations in claim 63, a claim which Sunstar in view of 5174959 was not applied.

Please Note: Amended claim 60 is not labeled correctly. Amended claim 60 was labeled "Previously presented" in the amendment dated December 20, 2007; this is incorrect. Claim 60 now recites a combination of claim limitations not previously presented. Claim 63 depended from claim 60; claim 66 depended from claim 60 and claim 73 depended from claim 66.

Therefore, the combination of claim limitations of claim 60, which now recites the limitations of claims 63, 66 and 73, is a new combination of claim limitations; claim 66 did not depend from claim 63.

Additionally, claims 64, 65 which depended directly upon claim 60 now recite a new combination of claim limitations in light of the amendment of claim 60 to recite the combination of claim limitations from claims 63, 66 and 73.

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Rejections Maintained/Response to Arguments

4. Applicant's arguments filed December 20, 2007 have been fully considered but they are not persuasive.

Claim Rejections - 35 USC § 103

- 5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 6. The rejection of claims 60, 63-69, 71-82 rejected under 35 U.S.C. 103 as being obvious over Pan (US PG-Pub 2004/0077093) in view of Arai et al (US PG Pub 2002/0068364) and US Pat. 4,407960 is traversed on the grounds that:
- The indicating agent is located within a passage of a tubular carrier portion.
- Pan does not disclose Michler's hydrol as an ammonia indicating agent;
- Arai et al sets forth a "lengthy list of various dye precursors" and mentions the generic class of triarylmethane dye precursors; and
- Tratnyek detects ethylene oxide and has nothing to do with ammonia detection; and
- 7. It is the position of the examiner that:
- The indicating agent of Pan is located within a passage of the tubular carrier portion,
 specifically a side passage, which has inlet and outlet portions that lead to and from the tubular carrier portion for capturing a gaseous breath sample and for releasing the breath sample.

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- Pan et al teaches [0060] "Any dye that is sensitive to and responds to changes in the amount of ammonia that permeates the pores of the polymer may be employed. In a preferred embodiment, the dye is a pH sensitive dye".
- Arai et al lists 14 dyes as ammonia indicators, one of which is triarylmethane dye. A list of 14 known dyes that will detect ammonia clearly teaches triarylmethane dyes for detection of ammonia. The MPEP section 2131.02, page 2100-72, column 1, states "A genus does not always anticipate a claim to a species within the genus. However, when the species is clearly named, the species claim is anticipated no matter how many other species are additionally named. Ex parte A, 17 USPQ2d 1716 (BD. Pat. App. & Inter. 1990)." Arai et al clearly names the species triarylmethane dyes for detection of ammonia. Arai et al 's list is as follows:
- "[0011] On the support, an indicator layer is provided. The indicator layer contains one or more compounds which change in absorption wavelength as a result of the reaction with gaseous ammonia (hereinafter, the compound is referred to as a dye precursor). The dye precursor which may be used in the analytical element of this invention includes leuco dyes, such as leucocyanine dye, nitro-substituted leuco dye and leucophthalein dye described in U.S. Pat. No. Re. 30,267, pH indicators, such as Bromophenol Blue, Bromocresol Green, Bromothymol Blue, Qinoline Blue and rosolic acid (see "Kagaku Dai-Jiten" (Chemical Dictionary) Kyoritsu, vol. 10, 63-65), triarylmethane dye precursors, leucobenzilidene pigments (see JP 1982-145273 A), diazonium salts and azo dye couplers, base bleachable dyes, and the like. "
- In response to Applicant assertion that Tratnyek only teaches the use of Michler's hydrol for detection of ethylene oxide, it is the position of the examiner that It has long been held that a reference must be evaluated in its entirety, not on the basis of its preferred embodiments or working examples. *In re Mills*, 470 F.2d 649, 651, 176 (USPQ 198 (CCPA 1972). Tratnyek teaches Michler's to be a visual chemical indicating composition for alkalylating agents, and ammonia is a type of alkylating agent. [53-Detailed Description] (Michler's). "A unique

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end use has thus been presented for these precursors which in the presence of acid are applied as visual chemical indicating compositions for <u>alkylating agents</u> such as ethylene oxide."

[23-Brief Summary] The indicating composition of this invention comprises a selected precursor or analog thereof of a triarylmethane dye, and an acidic constituent. The precursor and acidic constituent react to produce a color (e.g. blue)"; [19-Brief Summary] ...

"produced by the reaction of substrate, solvent and/or acid, the colorless leuco precursors undergo bond-breaking resulting in the aforedescribed resonance which thereby produces color upon the surface of the substrate." [3-Detailed Description] The precursor leuco baseforms and the benzhydrol intermediates, (such as Michler's hydrol) from which the dye radical is derived, are non-resonating forms and therefore non-color producing. A leuco base precursor has a central saturated carbon atom, as does the intermediate, Michler's hydrol. The precursors herein used may be considered to be alkylated precursors of the triarylmethane dyes."

- 8. Therefore Tratnyek teaches the disclose dyes as color indicating agents for any type of alkylating agent, of which ammonia is a known alkylating agent. Pan in view of Arai and Tratnyek obviate the instantly claimed invention as now claimed.
- 9. Claim 70 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pan (US PG-Pub 2004/0077093) in view of Arai et al (US PG Pub 2002/0068364) and US Pat. 4,407960, as applied to claims 60, 63-69, 71-81 above, further in view of US Pat. 7,052,854 was traversed with arguments addressing the rejection of claim 60, 63-69, 71-81. The examiner's responses are set forth above. This rejection is maintained for reasons of record and responses made of

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record in this office action.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to GINNY PORTNER whose telephone number is (571)272-0862. The examiner can normally be reached on flextime, but usually M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated

information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ginny Portner/ Examiner, Art Unit 1645 May 7, 2008

/Mark Navarro/

Primary Examiner, Art Unit 1645